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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,350	01/19/2002	Jeffrey O. Phillips	02936354	9247

7590

08/06/2003

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EXAMINER

FAN, JANE T

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/06/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/054,350

Applicant(s)

PHILLIPS, JEFFREY O.

Examiner

Jane T. Fan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) all are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1-6,8-14,17-23,25-32,34-36,75-83,85-88,91-97,99-106,108-126,129-135,137-144 and 146-356.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 8-14, 17-23, 25-32, 34-36, 151, 357, 75-83, 85-88, 91-97, 99-106, 108-112, 152, 358, 113-126, 129-135, 137-144, 146-191, 359-360, drawn to compositions and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent (or a single specific combination of buffer agents) for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion to a specific group of subject is required.
  - II. Claims 192-232, 361, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.
  - III. Claims 233-268, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.

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- IV. Claims 269-282, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.
- V. Claims 283-294, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.
- VI. Claims 295-304, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.
- VII. Claims 305-314, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.
- VIII. Claims 315-356, drawn to composition and method of use, classified in classes 424, 514, subclasses various. If this group is elected, an election of a single

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disclosed PPI, enteric coated or non-enteric coated, with a single disclosed buffer agent for treating a single disclosed acid related disease with one single dosage or multiple dosage or continuous infusion is required.

The inventions are distinct, each from the other because there are great many compositions with many different buffer agents and their combinations and permutations derived therefrom together with different kinds of PPI's and their uses of different methods of administering.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. It is noted that US Patent Application Publication 2002/0192299 ( examples 4-5), 6,248,363 by Patel et al. anticipates the claims (102a, 102g, 102f), WO94/02140 also anticipates the claims (102b).

Therefore, to argue that the compositions and methods of administering represent one inventive concept would be inconsistent with arguments with respect to their patentability over the art.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane T. Fan whose telephone number is 703-308-4705. The examiner can normally be reached on 7:00am-3:30pm, Monday-Thursday.

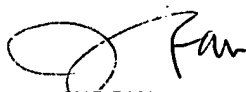
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4734 for regular communications and 703-308-4734 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jane T. Fan  
Primary Examiner  
Art Unit 1625

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August 5, 2003

  
JANE FAN  
PRIMARY EXAMINER  
GROUP 1200